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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/764,005	01/23/2004	Richard Lee	8070-002-US	8947
32301 7590 04/06/2009 CATALYST LAW GROUP, APC 9710 SCRANTON ROAD, SUITE S-170 SAN DIEGO, CA 92121				
EXAMINER				
CHOI, FRANK I				
ART UNIT		PAPER NUMBER		
1616				
MAIL DATE		DELIVERY MODE		
04/06/2009		PAPER		

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

### Office Action Summary

**Application No.**

10/764,005

**Applicant(s)**

LEE ET AL.

**Examiner**

FRANK I. CHOI

**Art Unit**

1616

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 26 April 2008.  
2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.  
3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-46 is/are pending in the application.  
4a) Of the above claim(s) 1-10, 12-23 and 38-46 is/are withdrawn from consideration.  
5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.  
6) ☒ Claim(s) 11, 24-37 is/are rejected.  
7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.  
8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.  
10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).  
11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
a) ☐ All b) ☐ Some \* c) ☐ None of:  
1. ☐ Certified copies of the priority documents have been received.  
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.  
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- 1) ☒ Notice of References Cited (PTO-892)  
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)  
3) ☐ Information Disclosure Statement(s) (PTO-8508)  
Paper No(s)/Mail Date \_\_\_\_\_  
4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date \_\_\_\_\_  
5) ☐ Notice of Informal Patent Application  
6) ☐ Other: \_\_\_\_\_

**DETAILED ACTION**

***Claim Rejections - 35 USC § 102/103***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 11, 24-31, 36, 37 are rejected under 35 U.S.C. 102(b) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over WO 83/02558.

WO 83/02588 expressly discloses a topical compositions containing retinoic acid, 10% minoxidil, water, ethanol cetrimonium chloride and cetyl alcohol (page 8) falling within the scope of applicant's claims.

Alternatively, at the very least the claimed invention is rendered obvious within the meaning of 35 USC 103, because the prior art discloses products that contain the same exact ingredients/components as that of the claimed invention. See *In re Fitzgerald*, 619 F.2d 67, 205 USPQ 594 (CCPA 1980). See also *In re May*, 197 USPQ 601, 607 (CCPA 1978).

Claims 11, 24-37 are rejected under 35 U.S.C. 103(a) as obvious over Imamura et al. (US Pat. App. Pub. 2004/0204433), WO 83/02588, Niemiec et al. (US Pat. App. Pub. 2002/0048558) and Remingtons.

Imamura et al. disclose a lotion containing 5g minoxidil, 10 g 1,3-butylene glycol, 5 g glycerol, 55 g ethanol, citric acid for pH of 6.0 and water sufficient to reach 100 ml, a lotion containing 5g minoxidil, 5 g glycerol, 5 g dipropylene glycol, 55 g ethanol, hydrochloric acid for pH of 6.0 and water sufficient to reach 100 ml, and a composition containing 10-50% by mass of water, 3% by mass or more of minoxidil, 8-30% by mass of polyhydric alcohol, pH of 5.5-6.5, where the polyhydric alcohol can be 1,3-butylene glycol, 1,3-butylene glycol and glycerol, dipropylene glycol and glycerol, where the composition can further contain alcohol, wherein the composition can contain a pH adjuster, wherein the composition can contain vitamin E acetate or glycyrrhetic acid (Table 1, Table 2, claims 1-12).

WO 83/02588 discloses a topical cream containing retinoic acid, 10% minoxidil, water, ethanol cetrimonium chloride and cetyl alcohol (page 8). It is disclosed that the topical compositions such as creams and lotions can contain from .01% to 30% minoxidil (Page 5).

Niemiec et al. disclose that anti-hair loss agents, such as minoxidil, can be mixed with anti-acne agents and depigmentation agents, such as azelaic acid (Paragraphs 0102, 0134, 0153, 0156).

Remingtons discloses that medicated creams and lotions are prepared by heating the oil phase ingredients and aqueous phase ingredients plus emulsifier each to 75 degrees and then mixing them together. It is disclosed that at this stage in the process, the medicinal ingredients are usually added as a concentrated slurry. It is disclosed that volatile or aromatic materials are generally added when the finished emulsion has cooled to about 35 degrees. It is disclosed that at this point, water may be added to compensate for any evaporative losses. It is disclosed that

while the product remains in bulk, quality control procedures are carried out, i.e for pH, active ingredients, etc. See pages 1576, 1577.

Imamura et al. disclose a composition containing 10-50% by mass of water, 3% by mass or more of minoxidil, 8-30% by mass of polyhydric alcohol, pH of 5.5-6.5, where the polyhydric alcohol can be 1,3-butylene glycol, 1,3-butylene glycol and glycerol, dipropylene glycol and glycerol, where the composition can further contain alcohol, wherein the composition can contain a pH adjuster, wherein the composition can contain vitamin E acetate or glycyrrhetic acid . The difference between Imamura et al. and the claimed invention is that Imamura et al. does not expressly disclose using at least 6.5% of minoxidil, the addition of azelaic acid or the process of preparation limitations. However, the prior art suggests the same as WO 83/02588 discloses topical compositions can contain up to 30% minoxidil; Niemiec et al. disclose that minoxidil can be combined with azelaic acid; and Remington's discloses the emulsions and lotions can be prepared by heating oil and water phases to 75 degrees, adding a slurry of the active ingredient, lower temperature to about 35 degrees and adding volatile ingredients and checking pH. As such, one of ordinary skill in the art would expect that topical compositions can be prepared having amounts of minoxidil within the claimed range, that azelaic can be combined with minoxidil and that preparation procedures including heating at 75 degrees, adding a slurry of active ingredients, cooling to about 35 degrees adding volatile ingredients and checking pH. See *In re Burhans*, 154 F.2d 690, 69 USPQ 330 (CCPA 1946) (selection of any order of performing process steps is prima facie obvious in the absence of new or unexpected results); *In re Gibson*, 39 F.2d 975, 5 USPQ 230 (CCPA 1930) (Selection of any order of mixing ingredients is prima facie obvious).

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The Examiner has duly considered the Applicant's arguments but deems them moot in light of the new grounds of rejection herein.

Therefore, the claimed invention, as a whole, would have been *prima facie* obvious to one of ordinary skill in the art at the time the invention was made, because every element of the invention has been collectively taught by the combined teachings of the references.

### ***Conclusion***

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

A facsimile center has been established in Technology Center 1600. The hours of operation are Monday through Friday, 8:45 AM to 4:45 PM. The telecopier number for accessing the facsimile machine is 571-273-8300.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Frank Choi whose telephone number is (571)272-0610. Examiner maintains a compressed schedule and may be reached Monday, Tuesday, Wednesday and Thursday, 6:00 am – 4:30 pm (EST).

If attempts to reach the Examiner by telephone are unsuccessful, the Examiner's Supervisor, Johann R. Richter, can be reached at (571)272-0646. Additionally, Technology Center 1600's Receptionist and Customer Service can be reached at (571) 272-1600.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Frank Choi  
Patent Examiner  
Technology Center 1600  
April 6, 2009

/Johann R. Richter/  
Supervisory Patent Examiner, Art Unit 1616